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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,826	08/14/2000	Eike Duwcing	50615	8623

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	13

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/636,826

Applicant(s)

DUWEING ET AL.

Examiner

Cynthia Collins

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

Applicant's request for reconsideration filed January 28, 2003, paper no. 12, has been entered. The request for reconsideration has been considered but does not place the application in condition for allowance for the following reasons:

Claim Rejections - 35 USC § 112

Applicant's arguments do not overcome the rejection of claims 55-61, 63-93 and 95-99 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed October 22, 2002. Applicant argues that the description of the V-ATPase subunit 3 isoform 2 promoter from *B. vulgaris* is sufficient to meet the written description requirement because gene orthologs have strong sequence homology and should possess the same function and expression pattern. The Office maintains that the disclosure of a single plant V-ATPase subunit c isoform 2 promoter from one plant species does not provide an adequate description of the claimed genus, as the disclosure of a one species of such a promoter does not describe the structure retained by other promoters encompassed by the genus.

Applicant's arguments do not overcome the rejection of claims 55-99 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA constructs comprising the elected promoter of the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO:1, expressing a heterologous gene, and producing a recombinant protein, does not

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reasonably provide enablement for DNA constructs comprising plant V-ATPase promoters generically or its functional equivalent, or plants, plant cells or protoplasts which are resistant to biotic or abiotic stress, or salt stress, for the reasons of record set forth in the office action mailed October 22, 2002. Applicant argues that one skilled in the art could easily isolate orthologs of the *B. vulgaris* V-ATPase subunit c isoform 2 promoter using the disclosed promoter sequence and techniques that are well known in the art. The Office maintains that it would require undue experimentation to practice the claimed invention as the specification does not provide sufficient guidance with respect to the structure of functional V-ATPase subunit c isoform 2 promoters for one skilled in the art to discriminate between operative and nonoperative embodiments of the claimed promoters on the basis of their nucleotide sequence.

Applicant's arguments do not overcome the rejection of claims 55 and 62 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "functional equivalent", for the reasons of record set forth in the office action mailed October 22, 2002. Applicant's argument filed January 28, 2003, that the specification defines "functional equivalent" was previously addressed. The Office maintains that the definition in the specification does not clarify whether "functional equivalent" in claim 55 refers to the promoter or to a DNA construct. Furthermore, if "functional equivalent" refers to the promoter, the definition in the specification also does not clarify what level of promoter activity would be functionally equivalent. It is unclear whether functional equivalent means any promoter activity or the same level of promoter activity as the recited promoter.

Applicant's arguments do not overcome the rejection of claims 55, 61 and 74 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "gene", for the reasons of

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record set forth in the office action mailed October 22, 2002. Applicant argues that the definition of gene as used in the claims would be that given by one possessing the ordinary level of skill in the art. The Office maintains that the definition of gene given by one possessing the ordinary level of skill in the art would not exclude promoter sequences, noncoding sequences and termination sequences.

Applicant's arguments do not overcome the rejection of claim 59 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "different manner", for the reasons of record set forth in the office action mailed October 22, 2002. Applicant argues that the claim is not indefinite as the second additional promoter simply has to be regulated in a different manner. The Office maintains that claim 59 is indefinite as the manner in which the first and second promoters are regulated cannot be discerned from the claim.

Applicant's arguments do not overcome the rejection of claim 61 under 35 U.S.C. 112, second paragraph, as being indefinite in the manner of recitation of specific heterologous genes, in the recitation of "a resistance-mediating gene", and in the recitation of "other medicinal, agronomical or other interest", for the reasons of record set forth in the office action mailed October 22, 2002. Applicant argues that the claim is not indefinite as Applicant intends that the claim be directed to any type of resistance known in the art. The Office maintains that the claim is not currently limited to any type of resistance known in the art, and is indefinite in that "other" implies that the selection marker and the resistance-mediating gene fall within the categories "medicinal, agronomical or other interest". The Office further maintains that the number and nature of the alternatives present in "other medicinal, agronomical or other interest" is unclear.

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Applicant's arguments do not overcome the rejection of claims 74 and 78 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "gene which has been transformed by means of the DNA construct". Applicant argues that since the method of claim 75 transforms a plant cell and this transformation is accomplished with a DNA construct it is immaterial whether or not the DNA construct is a product. The Office maintains that a DNA construct is not a means of transformation.

Applicant's arguments do not overcome the rejection of claims 96-97 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "which is", for the reasons of record set forth in the office action mailed October 22, 2002. Applicant argues that which is refers to both a plant cell and a protoplast. The Office maintains that the language of the claims remains unclear with respect to whether "which is" refers to a plant cell, a protoplast, or both.

Applicant's arguments do not overcome the rejection of claims 90 and 91 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Applicant argues that expressing the DNA construct produces the recombinant protein. The Office maintains that in the absence of a recombinant protein expression step the method does not accomplish the purpose set forth in the preamble. Furthermore, expression of the DNA construct would result in the production of RNA, not protein.

Applicant's arguments do not overcome the rejection of claims 92-95 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Applicant argues that one of ordinary skill in the art would recognize that the key step is the transformation of the plant with

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the construct, and that expression is understood as the preamble states "a method of transformation". The Office maintains that in the absence of an expression step the method does not accomplish the purpose set forth in the preamble. Furthermore, transformation of a plant with a construct would not necessarily result in expression of the construct in the transformed plant.

Claim Rejections - 35 USC § 102

Applicant's arguments do not overcome the rejection of claims 55-56, 58-63, 65-67, 69, 74, 76, 77, 82, 84-85 and 90 under 35 U.S.C. 102(b) as being anticipated by Struve et al. (The Journal of Biological Chemistry, Vol. 265, No. 14, May 15, 1990, pages 7927-7932), for the reasons of record set forth in the office action mailed October 22, 2002. Applicant's argument filed January 28, 2003, that the promoter taught by Struve et al. cannot be considered a functional equivalent because the promoter taught by Struve et al. would not be functionally equivalent to the V-ATPase subunit 3 isoform 2 promoter disclosed in the specification was previously addressed. The Office maintains that details regarding the function of the specific V-ATPase subunit 3 isoform 2 promoter disclosed in the specification do not limit the function of the claimed promoter. This rejection is maintained.

Claim Rejections - 35 USC § 103

Applicant's arguments do not overcome the rejection of claims 55-99 under 35 U.S.C. 103(a) as being unpatentable over Struve et al. (The Journal of Biological Chemistry, Vol. 265, No. 14, May 15, 1990, pages 7927-7932), for the reasons of record set forth in the office action mailed October 22, 2002. Applicant argues that the promoter taught by Struve et al. cannot be



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